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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,961	09/29/2008	John A. St. Cyr	365.0006 0101	6292

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EXAMINER	
BLAND, LAYLA D	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
05/10/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,961	ST. CYR ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8 and 21-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/24/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a national stage entry of PCT/US2005/001435 filed January 14, 2005, which claims benefit of U.S. Provisional Application No. 60/536,460 filed January 14, 2004.

Applicant's amendment and election without traverse of Group I in the reply filed on April 28, 2011 is acknowledged. Claims 8 and 21-38 are pending and are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment submitted April 28, 2011 introduced new claims 21-38, which limit original claim 8 drawn to administration of ribose to a mammal suffering from sepsis. Applicant indicated that support for the new claims could be found in the original claims and on page 24 of the specification. The original claims recite dosage forms, dosages, and routes of administration for reducing the recovery time of a mammal undergoing general anaesthesia, but do not

recite those details for enhancing the recovery from sepsis. Page 24 of the specification states that ribose administration can be used as an adjunct to usual therapies for sepsis, but page 24 provides no details about dosage, etc. for treatment of sepsis. The detailed information with respect to dosage and timing of administration of ribose as recited in the new claims is given in the specification specifically for recovery after general anaesthesia, as mentioned on pages 1-23 of the specification. Page 24 of the specification mentions sepsis independently of general anaesthesia, and recites the use of ribose in cases where antibiotic therapy has failed, but does not recite concurrent treatment with antibiotic and ribose. The examiner was unable to locate any recitation in the specification to indicate that the same detailed dosage information useful for recovery after general anaesthesia would be the same for recovery from sepsis. Thus, the skilled artisan would not be apprised that Applicant had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 21-22, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by St. Cyr et al. (US 6,159,942, December 12, 2000, PTO-1449).

St. Cyr teaches oral administration of ribose [column 3, line 16] to a subject suffering from sepsis [column 3, lines 43-46]. The preferred dosage is 1-20 or 4-8 grams per day, given 1, 2, or 3 times throughout the day [column 4, lines 39-57].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Cyr et al. (US 6,159,942, December 12, 2000, PTO-1449) in view of St. Cyr et al. (US 6,218,366, April 17, 2001, PTO-1449) and Taylor et al. (Am J Physiol Lung Cell Mol Physiol 275:L139-L144, 1998).

St. Cyr ‘942 teaches oral administration of ribose to subjects suffering from sepsis, as set forth above. St. Cyr '942 does not teach intravenous administration or combined administration with glucose.

St. Cyr ‘366 teaches administration of ribose to subjects experiencing a hypoxic condition [see abstract]. The ribose can be administered orally, intravenously, or

intraperitoneally [claim 9] at a dosage of 1-60 grams [claim 3]. In one example, 10% ribose was administered intravenously with 5% glucose [column 10, lines 54-60].

Taylor teaches that tissue hypoxia is likely to occur during sepsis [page L139, second column, second paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer intravenous ribose to a subject suffering from sepsis. St. Cyr '942 teaches oral administration of ribose to subjects suffering from sepsis and St. Cyr '366 also teaches administration of ribose and provides guidance for intravenous administration including glucose. Taylor teaches that hypoxia is likely to occur during sepsis, so the skilled artisan would conclude that the guidance provided by St. Cyr '366, directed to treating hypoxic conditions, would be relevant to treatment of sepsis. St. Cyr '366 does not teach the dosage of ribose in mg/kg/hour, but provides general guidance for the amount and concentration of ribose to be used. Thus, the skilled artisan would optimize the amount using routine optimization. See MPEP 2144.05: "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 245 (CCPA 1955)."

Claims 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Cyr et al. (US 6,159,942, December 12, 2000, PTO-1449) in view of Cunha (Med Clin North Am. 1995 May; 79(3):551-8, abstract only); or over St. Cyr et al. (US 6,159,942, December 12, 2000, PTO-1449) in view of St. Cyr et al. (US 6,218,366, April 17, 2001, PTO-1449) and Taylor et al. (Am J Physiol Lung Cell Mol Physiol 275:L139-L144, 1998 as applied to claims 23-28 above, and further in view of Cunha (Med Clin North Am. 1995 May; 79(3):551-8, abstract only).

St. Cyr '942 and St. Cyr '366 teach or suggest administration of ribose to subjects suffering from sepsis, as set forth above, but do not teach administration of antibiotic.

Cunha teaches that antibiotic therapy is critical to treatment of the septicemic patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the method as discussed above, and to also administer antibiotic to the subject. The cited references teach or suggest administration of ribose to a subject suffering from sepsis, and antibiotic therapy is also used to treat sepsis, as taught by Cunha. The skilled artisan would administer ribose to treat hypoxia caused by the sepsis and would administer antibiotic to treat the infection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 21-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,218,366

in view of Taylor et al. (Am J Physiol Lung Cell Mol Physiol 275:L139-L144, 1998), and further in view of Cunha (Med Clin North Am. 1995 May; 79(3):551-8, abstract only.

The '366 patent claims administration of ribose to increase tolerance to hypoxia in a subject, but does not claim administration to a patient suffering from sepsis. Taylor teaches that tissue hypoxia is likely to occur during sepsis [page L139, second column, second paragraph]. Thus, it would have been obvious to treat patients undergoing hypoxia due to sepsis. Cunha teaches that antibiotic therapy is critical to treatment of the septicemic patient. Thus, the skilled artisan would administer antibiotics to the subject suffering from sepsis because antibiotics are used to treat that condition. The '366 patent claims oral or intravenous administration at a dosage of 1-60 grams. The skilled artisan would use this guidance to optimize the dosage of ribose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Primary Examiner, Art Unit 1623